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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

26474 7590 08/27/2002

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER
WARE, TODD

ART UNIT	PAPER NUMBER
1615	4

DATE MAILED: 08/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/811,546	Applicant(s) KOLTER ET AL.	
	Examiner Todd D Ware	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 1-25-02 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of preliminary amendment filed 3-20-01 and information disclosure statement filed 1-25-02 is acknowledged. Claims 3-21 have been amended as requested. Claims 1-21 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 requires "other conventional excipients." Recitation of "other" is indefinite since the claim(s) include(s) elements not actually disclosed (those encompassed by "other"), thereby rendering the scope of the claim(s) unascertainable. Recitation of "conventional" is a relative term that does not allow one to determine the breath of the claims. What is conventional today may not be conventional tomorrow. Also, to whom are the excipients "conventional?"

4. Regarding claims 6, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation cellulose derivatives, and the claim also recites methylcellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethylcellulose, carboxymethylcellulose which are narrower statements of the range/limitation. Claim 7 also recites the broad recitation starch derivatives as well as carboxymethyl starch and degraded starch which are narrower statements of the range/limitation. Also, claim 8 recites the broad recitation cellulose derivatives, and the claim also ethylcellulose, cellulose acetate, cellulose acetate phthalate, cellulose acetate succinate, hydroxypropylmethylcellulose acetate phthalate, hydroxypropylmethylcellulose acetate succinate which are narrower statements of the range/limitation. Claim 8 also recites the broad recitation acrylic ester/methacrylic ester copolymers as well as methyl methacrylate/ethylacrylate copolymers, ammoniomethacrylate copolymer type A and type B, methacrylic acid/acrylic ester

copolymers which are narrower statements of the range/limitation. Claim 8 also recites the broad recitation methacrylic ester/acrylic ester copolymers as well as methacrylic acid/ethylacrylate copolymers in particular. The phrase " in particular " renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

6. Claims 20 and 21 provide for the use of oral dosage forms for producing drugs and for delayed release of active agents, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

7. Claims 20 and 21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 4-7, and 9-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grabowski et al (5,490,990; hereafter '990).

10. '990 discloses delayed release dispersions of vinylpyrrolidone/vinylacetate with a water soluble polymer lubricant. Column 3, lines 45-67 discloses inclusion of polyvinyl alcohol or a cellulose derivative in the formulation.

11. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kolter et al (DE 197 09 663; hereafter '663 –US 6,066,334 is relied upon as an English translation).

12. '663 discloses delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures. The instant water soluble and lipophilic polymers and water-soluble swelling polymers are also disclosed and ingredients (abstract; C 2, L 23-C 5, L 5; examples; claims.

13. Claims 1-5, 8-12, and 15-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ortega (4,837,032; hereafter '032).

14. '032 discloses delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures with water-soluble polymers (abstract; C 2, L 15-42; C 3, L 1-68; examples). The amounts of ingredients are within the instant claimed ranges.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1, 4-7, and 9-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grabowski et al (5,490,990; hereafter '990).

18. '990 teaches delayed release dispersions of vinylpyrrolidone/vinylacetate with a water soluble polymer lubricant. Column 3, lines 45-67 teaches inclusion of polyvinyl alcohol or a cellulose derivative in the formulation. Manipulation of amounts of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting amounts in accordance with requirements to maintain

anti-blocking properties of the composition while adjusting other contents of the formulation such as amount of drug or additives.

19. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter et al (DE 197 09 663; hereafter '663 –US 6,066,334 is relied upon as an English translation).

20. '663 teaches delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures. The instant water soluble and lipophilic polymers and water-soluble swelling polymers are also disclosed and ingredients (abstract; C 2, L 23-C 5, L 5; examples; claims. Manipulation of amounts of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting the retardant/disintegration effects of the composition.

21. Claims 1-5, 8-12, and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega (4,837,032; hereafter '032).

22. '032 teaches delayed release dosage forms having polyvinylpyrrolidone and polyvinylacetate polymer mixtures with water-soluble polymers (abstract; C 2, L 15-42; C 3, L 1-68; examples). The amounts of ingredients are within the instant claimed ranges. Manipulation of amounts of ingredients would have been obvious to one skilled in the art at the time of the invention with the motivation of adjusting the binding effects of the composition.

Double Patenting

23. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,066,334. Although the conflicting claims are not identical, they are not patentably distinct from each other because while '334 recites rapid release, this is a subjective term and it also requires that release occurs up to an hour later. This is interpreted as delayed release. No other characteristics appear to differentiate the claims.

Conclusion

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone

numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
August 26, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600